



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Winfried Edelmann *et al.*

Serial No.: 09/658,969

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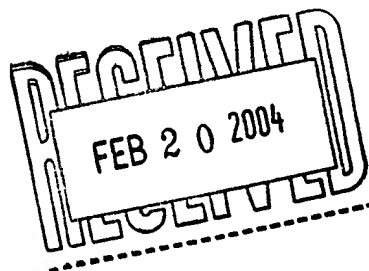
For: *METHODS FOR MODULATING THE  
ACTIVITY OF MSH5*

Attorney Docket No.: AHN-001DV2

Group Art Unit: 1617

Examiner: San Ming R. Hui

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



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By:

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RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This is in response to the Restriction Requirement dated August 6, 2003 (Paper No. 19). A separate petition for the appropriate extension of time in which to respond is being filed concurrently herewith.

In the Restriction Requirement, the Examiner has stated that “Applicant is required under 35 U.S.C. 121 to elect i) a single disclosed species of a method of modulating fertility and meiosis (*e.g.*, either enhancing fertility or contraception) **and** ii) a single disclosed compound of modulating fertility and meiosis, even though this requirement is traversed.”

With respect to the first requirement, Applicants hereby elect the species of “contraception,” *for search purposes only*, as the species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

With respect to the second requirement, Applicants hereby *traverse* the requirement and respectfully submit that an election of certain small molecules has been previously made. In response dated August 2, 2002 to a Restriction Requirement dated June 4, 2002 (Paper No. 11), Applicants elected (with traverse) claim 25, drawn to small molecules. Subsequently, telephonic interviews were conducted between Supervisory Patent Examiner Christopher Low, Examiner Samuel Liu, and Applicants' attorney on August 7 and 8, 2003, during which the recitation of “small molecule” was clarified to include “small organic molecules.” The term was further clarified such that it *does not* include oligonucleotides, DNA, RNA, peptides or proteins. The interviews are summarized in an Interview Summary (Paper No. 14). Accordingly, in order to be considered responsive to the instant Restriction Requirement, Applicants reiterate the election of small molecules which are *not*

oligonucleotides, DNA, RNA, peptides or proteins. Applicants respectfully submit that the instant species election requirement is improper.

Claim 15 is directed to a method for modulating fertility in a subject comprising contacting MSH5 or a cell expressing MSH5 with a compound in an amount sufficient to modulate MSH5 expression or activity. Dependent claim 25 is directed to the method of claim 15, wherein the compound is a small molecule. Claim 32 is directed to a method for inhibiting MSH5 expression or activity in a subject comprising administering to the subject an effective amount of an inhibitor of MSH5 expression or activity. Claim 33 is directed to a method for preventing fertilization in a subject by administering to the subject an effective amount of an inhibitor of MSH5 expression or activity. Claim 34 is directed to a method for modulating meiosis in a subject comprising administering to the subject an effective amount of an inhibitor of MSH5 expression or activity.

The pending claim are directed to *methods* for modulating fertility in a subject, preventing fertilization in a subject, and modulating meiosis in a subject by modulating MSH5 expression or activity. The instant claims are not composition claims directed to a novel compound. The novelty of Applicants invention lies in the discovery of the role of MSH5 in modulating fertility and meiosis, rather than with any specific compound.

As the M.P.E.P. states:

[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803.

Applicants respectfully submit that the pending claims are not overly broad and that a search and examination of the pending claims would only include an organic small molecule which modulates MSH5 expression or activity resulting in the modulation of contraception,

modulation of meiosis, or prevention of fertilization in a subject. Applicants respectfully submit that this search can be made without a serious burden. In other words, the search would include only those non-peptide, non-protein, non-DNA, non-RNA, non-oligonucleotide, organic small molecules which function to directly affect, *e.g.*, inhibit MSH5 expression or activity, to thereby inhibit or prevent fertilization or result in contraception in a subject.

Furthermore, a substantive Office Action (Paper No. 14, dated January 15, 2003) has already been issued in the instant application. Accordingly, Applicants respectfully submit that a search and examination of the pending claims has already been performed by the Examiner.

#### SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,



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Dated: **February 6, 2004**